IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

JIM HOOD, ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, *ex rel.* THE STATE OF MISSISSIPPI Plaintiff, vs. SANOFI, S.A. f/k/a SANOFI AVENTIS S.A., et al., Defendants.	)	Case No. 3:18-cv-842CWR-FKB

SANOFI'S NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, Defendants Sanofi U.S. Services, Inc., Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S. ("Sanofi") hereby give notice of the removal of this action, styled *Jim Hood, Attorney General of the State of Mississippi, ex rel. The State of Mississippi v. Sanofi S.A., et al.*, Case Number G2018-1453, from the Chancery Court of Hinds County, Mississippi to the United States District Court for the Southern District of Mississippi.

INTRODUCTION

Plaintiff's entire case arises from and depends overwhelmingly on complex questions of federal law. While Plaintiff claims that its action is one sounding in state law, its pleading reveals a different story. Plaintiff's claim includes repeated references to and reliance on purported duties required under the federal Food and Drug Administration's ("FDA") regulatory program for prescription drug products, and purported violations of those duties. Plaintiff also

elects to proceed under a cause of action that mandates interpretation of yet another federal agency's law and regulations—the Federal Trade Commission. Removal of this case to federal court does not disturb the federal-state judicial balance, as a federal MDL Court has been managing thousands of cases with nearly identical factual and legal allegations for more than two years. As Sanofi demonstrates below, this action meets all requirements necessary for removal.

I. INFORMATION AND BACKGROUND

1. On October 26, 2018, Plaintiff filed this civil action in the Hinds County Chancery Court. The case is styled *Jim Hood, Attorney General of the State of Mississippi, ex rel. The State of Mississippi, v. Sanofi S.A. f/k/s Sanofi Aventis S.A.; Aventis Pharma S.A.; Sanofi U.S. Services, Inc. f/k/a Sanofi-Aventis U.S., Inc.; Sanofi-Aventis U.S. LLC; Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S.; Sandoz, Inc.; Accord Healthcare, Inc.; McKesson Corporation d/b/a McKesson Packaging; Hospira, Inc.; Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.; Sun Pharma Global FZE; Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd.; Pfizer, Inc.; Actavis LLC f/k/a Actavis, Inc.; Actavis Pharma, Inc.; Sagent Pharmaceuticals, Inc., and Fictitious Defendants A-Z*, Case Number G2018-1453. As required by 28 U.S.C. § 1446(a) and Local Uniform Civil Rule 5(b), attached as Exhibit A is the entire State Court Record.

2. On November 5, 2018, Plaintiff served a copy of the Complaint and Summons on Sanofi.[1] As required by 28 U.S.C. §1446(a) and Local Uniform Civil Rule 5(b), Exhibit A contains copies of the Complaint and Summons that have been served upon Sanofi.

[1] Plaintiff served Sanofi's United States entities (Sanofi U.S. Services, Inc.; Sanofi-Aventis U.S. LLC; and Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S.) on November 5, 2018. Although also named in this suit, Plaintiff has yet to serve Sanofi's international entities (Sanofi S.A. and Aventis Pharma S.A.) with the subject Complaint. Nothing herein waives service of process of Sanofi S.A. or any entity that has not been served.

3. Plaintiff brings this suit against Sanofi and several other pharmaceutical manufacturers or distributors (collectively "Defendants") alleging unfair, deceptive, false and fraudulent acts in violation of the Mississippi Consumer Protection Act ("MCPA"), §§ 75-24-1 *et seq*. premised on Sanofi's and other Defendants' product labeling and marketing materials related to Taxotere,[2] a chemotherapy agent. (*See* Compl. at ¶¶ 231, 233, 234.)

4. This case is removable pursuant to 28 U.S.C. § 1331 because the action arises under federal law. Plaintiff's claim is based on Defendants' purported violations of FDA statutes and regulations that govern and regulate pharmaceutical labeling, warnings, and instructions. Plaintiff not only relies on FDA statutes, regulations, and purported violations of the regulatory regime, which unequivocally includes the interpretation, decision, and application of federal law, but Plaintiff's claim also implicates federal jurisdiction by electing to proceed under the MCPA. These issues present substantial federal questions and render this action removable pursuant to 28 U.S.C. § 1331.

II. REMOVAL IS PROCEDURALLY PROPER

A. The Notice of Removal Is Timely.

5. This removal is timely under 28 U.S.C. § 1446(b)(1). Sanofi files this Notice of Removal within 30 days of November 5, 2018, the date of service of the initial pleading upon Sanofi's United States entities (Sanofi U.S, Services, Inc.; Sanofi-Aventis U.S. L.L.C.; and Sanofi-Aventis U.S. L.L.C. d/b/a Winthrop U.S.).

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[2] Taxotere is also known by its generic name, Docetaxel. Plaintiff's allegations involve Taxotere, Docetaxel, Docetaxel injection, Docetaxel Injection Concentrate, and Docefrez (collectively referred to as "Taxotere" herein).

B. Venue Is Proper in The Southern District of Mississippi, Northern Division.

6. The United States District Court for the Southern District of Mississippi, Northern Division is the proper venue for removal under 28 U.S.C. § 1441(a). The Northern Division of the Southern District encompasses Hinds County pursuant to 28 U.S.C. § 104(b)(1).

7. In accordance with 28 U.S.C. § 1446(b)(2)(A), all Defendants that have been served have consented to the removal.[3,4] These consents are attached as Exhibits B through G.

III. FEDERAL QUESTION JURISIDCTION

8. District courts have subject matter jurisdiction over cases involving federal questions – *i.e.*, "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Federal question jurisdiction is present "when a federal question is presented on the face of the plaintiffs' properly pleaded complaint." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). This Court has federal question jurisdiction in this matter pursuant to 28 U.S.C. § 1331 and 28 U.S.C. §1441.

9. A case that invokes a state law cause of action is nonetheless removable if it involves a substantial federal question which is "actually disputed and substantial," and "which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods. Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). Considering whether a state quiet title action necessarily depended on the interpretation of a federal IRS notice statute, the Supreme Court found that it is a "commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the

[3] All defendants expressly reserve the right to assert all applicable defenses under Civil Rule 12(b) as well as all applicable affirmative defenses.

[4] Sun Pharma Global FZE has been named by plaintiff in this litigation but is a foreign company incorporated under the laws of the United Arab Emirates and has not been served with process of the subject Complaint. Nothing herein waives service of process of Sun Pharma Global FZE or any defenses.

experience, solicitude, and hope of uniformity that a federal forum offers on federal issues..." *Id.* at 312. Even though state law may create the cause of action, the Fifth Circuit has found that federal question jurisdiction still exists where "(1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Bd. Of Comm'rs of the Se. La. Flood v. Tenn. Gas Pipeline Co.*, 850 F.3d 714, 721-22 (5th Cir. 2017).

A. Plaintiff's Complaint Invokes Federal Question Jurisdiction by Making the FDA Regulatory Program a Basis for Its Complaint. Specifically, the Outcome of Plaintiff's Claim Depends upon the Resolution of Substantial and Disputed Federal Questions.

10. The viability of Plaintiff's self-styled "state law" claim is predicated upon substantial and significant questions of federal law. Plaintiff's Complaint, over and over, asserts obligations incumbent upon Sanofi derived from a complex federal regulatory program, specifically FDA statutes and regulations related to product labeling, warnings, and instructions. Here, the substantial and disputed issues require the court to determine what federal law requires of Sanofi, whether they complied with said federal laws, and whether that conduct can be subject to state law restraint given the FDA's extensive regulatory framework. Nearly one-third of Plaintiff's numbered allegations quote, invoke, mention or impliedly concern federal regulations. This case requires removal to avoid a collateral and non-uniform attack on that longstanding and extensive regulatory framework. *See Bader Farms, Inc. v. Monsanto Co.*, 2017 WL 633815, at *3 (E.D. Mo. Feb. 16, 2017) (finding federal jurisdiction under *Grable* even where just one claim involved a substantial federal question – in this case, that substantial federal question existed where the outcome of the claim necessarily depended upon the interpretation and application of the federal regulatory process).

11. Plaintiff's complaint is devoid of state law authority requiring Sanofi to identify, report, or evaluate studies for the labeling and/or manufacturing of Taxotere. To the contrary, Plaintiff expressly identifies federal law as its source for the requirements it alleges should be imposed on Sanofi – violations of which it argues give rise to state-law liability. Compl. at ¶¶ 78-83. And it is the federal system that Plaintiff concedes imposes rules regarding whether, when, and how clinical studies and other information may prompt changes to the labeling and marketing of pharmaceutical drugs regulated by the FDA. *See, e.g., id.* at ¶ 81 ("All changes to labeling require FDA assent."). Since Sanofi's liability under the MCPA is based on the regulatory framework and alleged violations of federal law, a court would have to review that complex federal program and adjudicate whether Sanofi violated those federal requirements in order to decide state-law liability.

12. Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") to provide for uniform, nationwide regulation of pharmaceutical products. Pursuant to 21 C.F.R. § 201 *et seq.*, the FDA Center for Drug Evaluation and Research has broad power to regulate the approval of prescription drugs, and to control what content and format is included in all prescription medication labels, advertising, and packaging. *See* 21 C.F.R. § 201(e)(4). The FDA is also in charge of reviewing clinical research and taking appropriate action in the marketing, advertising, labeling, and packaging of prescription medication. 21 C.F.R. § 201(b)(1). The FDA has exclusive authority to enforce the FDCA. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for enforcement, or to restrain violations, of this chapter [the FDCA] shall be by and in the name of the United States."). And the FDA controls all aspects of the description, format, contents, and warnings including prescription drug labeling and has implemented a strict regimen in order to make any label changes. *See* 21 C.F.R. § 201.100(c); 201.56; 201.57; 314.70; 601.12. Speaking

for a unanimous Court in *Grable*, Justice Souter emphasized, "[w]e hold that the national interest in providing a federal forum ... is sufficiently substantial to support the exercise of federal question jurisdiction over the disputed issue on removal." 545 U.S. at 310. Given the exclusive jurisdiction of the FDA over all issues related to the timing, format and content of such warnings, it is in the national interest that challenges to the FDA's determinations and process be resolved in federal court to preserve uniform decisions and application.

13. The Fifth Circuit recently affirmed the denial of remand in a similarly-situated case, holding that the plaintiff's allegations based on state law necessarily included federal issues to the point of raising a federal question. *Tenn. Gas Pipeline*, 850 F.3d at 723. In *Tenn. Gas Pipeline*, the plaintiff brought suit in Louisiana state court against 97 entities who were involved in the exploration for and production of oil reserves off the southern coast of the United States. *Id*. at 720. Within its complaint, plaintiff asserted the violation of "a longstanding and extensive regulatory framework under both federal and state law" that protects against the effects of dredging activities and establishes a legal duty to which all the defendants were bound, specifically naming four federal statutes which defendants had allegedly violated. *Id*. The defendants removed the action contending that plaintiff's state law negligence and nuisance claims would necessarily involve the interpretation of federal law and the Fifth Circuit agreed, finding that the plaintiff's claims "cannot be resolved without a determination whether multiple federal statutes create a duty of care that does not otherwise exist under state law." *Id*. at 723. The Fifth Circuit affirmed by holding that the key federal question inquiry is "the importance of the issue to the federal system as a whole," *id*. at 723, and that "the scope and limitations of a complex federal regulatory framework are at stake in this case." *Id*. at 725. *See also Smith v. Barret Daffin Frappier Turner & Engel, L.L.P.*, 735 F. App'x 848, 854 (5th Cir. 2018) (even

though plaintiffs intended to bring an action only under the state debt collection act, removal on federal question grounds was appropriate where plaintiffs "invoked the federal [debt collection] statute—by name and number—and alleged conduct that violated that act."); *Magee v. Miss. Dept. of Public Safety*, 2011 WL 13229637 (S.D. Miss. July 25, 2011) (removal of state law breach of contract case on federal question grounds was appropriate where "plaintiffs' ability to recover is contingent primarily on establishment that [the defendant] violated the [federal Fair Labor Standards Act].").

14. Similar to the allegations in *Tennessee Gas Pipeline,* the allegations here rely on defendants' purported violation of federal statutes. Plaintiff premises its claim on allegations that Sanofi falsely promoted and advertised Taxotere in violation of the FDCA. To support its allegations, Plaintiff includes four FDA letters concerning Sanofi's promotional materials that purportedly demonstrate wrongful conduct (Compl. at ¶¶ 154-57, 159, 168), and contends that Sanofi failed to disclose/report certain information as required by the FDA. Compl. at ¶¶ 1, 218. Plaintiff cannot prevail upon its claim without (1) establishing what duties the FDCA imposes on Sanofi; (2) proving that Sanofi's conduct was in contravention of the FDCA; (3) proving that the FDA would have actually allowed the Plaintiff's contemplated changes to the labeling, packaging, and advertising that it contends Mississippi law requires; and (4) establishing that the relief requested, especially injunctive relief, does not conflict with the FDA regulatory program.[5]

15. Plaintiff raises substantial federal questions that involve the scrutiny and application of federal laws and federal regulations. The core issues of federal law—whether

[5] Sanofi notes that these arguments apply with equal force to the other defendants in the case, as quasi-generic pharmaceutical manufacturers who are likewise subject to strict regulation under the FDCA and related FDA regulations. Indeed, Plaintiff relies on its alternate regulatory approvals to demonstrate alleged state law liability in the same way that Plaintiff does for Sanofi. *See, e.g.*, Complaint ¶66 (referencing FDCA Sections 505(b)(1), 505(b)(2), and 505(j)). Simply put, with respect to *every* defendant in this case, there is no way to resolve Plaintiff's claims without a detailed assessment of the nature and extent of each defendant's compliance with FDA regulations.

Sanofi misrepresented that its products' labels and promotional materials contained the appropriate format and content and the timing of such warnings—are disputed here. Among other things, Plaintiff will be forced to prove its allegations that Sanofi misrepresented its products and that the FDA requires the type and timing of reporting alleged. *See, e.g.,* Compl. at ¶ 218 (alleging that FDA required certain types and timing of reporting). That is, disputed federal issues exist because Sanofi does "not concede that a federal law imposes obligations of [it or Defendants] in the manner and to the extent that the plaintiff has alleged." *See Tenn. Gas Pipeline,* 850 F.3d at 723 (5th Cir. 2017). Resolution of Plaintiff's case requires analysis and interpretation of important issues to the federal system as a whole.

16. The federal government's historical role of protecting and enforcing FDA labeling standards gives it a "direct interest in the availability of a federal forum" for any litigation related to those statutes. *Grable*, 545 U.S. at 315. Under the FDCA, the FDA has the statutory authority to regulate the labeling of prescription drugs in a manner that results in preemption of conflicting state law claims. Congress delegated the FDA broad authority to "protect the public health" by ensuring that prescription drug labeling contains appropriate "directions of use and cautionary statements." 21 U.S.C. § 353(b)(2). As noted earlier, the FDA controls all aspects of the description, format, contents, and warnings including prescription drug labeling and has implemented a strict regimen in order to make any label changes. *See* 21 C.F.R. § 201.100(c); 201.56; 201.57; 314.70; 601.12.

17. It is important that these issues be resolved in a federal forum and not litigated piecemeal in state court. Litigating this case in a state court runs the risk of the state court applying federal requirements inconsistently to both the FDA and federal courts. Federal courts often hear challenges involving the scope and extent of FDA regulations of pharmaceutical

manufacturers and thus, federal jurisdiction in this case "would not materially affect, or threaten to affect, the normal currents of litigation." *Grable,* 545 U.S. at 319.

B. Federal Question Jurisdiction is Also Appropriate Because the MCPA Mandates Interpretation and Application of Federal Law and FTC Regulations.

18. Just as the Attorney General's "collateral attack" on a "longstanding and extensive regulatory framework" is inherently intertwined with laws of the United States, the choice to proceed under the MCPA, Miss. Code §§ 75-24-1 *et seq.*, also implicates federal question jurisdiction. Section 75-24-3(c) of the MCPA states in its entirety:

> It is the intent of the Legislature that in construing what constitutes unfair or deceptive trade practices that the courts will be guided by the interpretations given by the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 USCS 45(a)(1)) as from time to time amended.

19. Application of the MCPA must therefore be guided not only by a federal statute, but also by interpretations of that statute by the federal judiciary and a federal agency. A federal question is therefore raised through the incorporation of federal common law and decision-making into the state statute, and thus subjects Plaintiff's action to Section 1331 subject matter jurisdiction under the *Grable* test.

20. Although no Mississippi court has ruled directly on whether Section 75-24-3(c) of the MCPA establishes federal question jurisdiction, two court decisions applying the consumer protection statutes of other states provide instructive guidance. Both of those decisions held that those state statutes conferred federal question jurisdiction because they employed the same incorporation of FTC decisions and case law that Section 75-24-3(c) does. Like the case at bar, both of these cases involved attorney general civil actions—one in West Virginia and one in New Mexico—brought against pharmaceutical companies alleging violation of the respective states' consumer protection statutes.

21. In *West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 2008 WL 4449655 (E.D.N.Y. Sept. 30, 2008), the attorney general of West Virginia brought suit against the manufacturer of the antipsychotic drug Zyprexa, seeking injunctive relief and restitution under the West Virginia Consumer Credit and Protection Act, as well as causes of action under Medicaid and West Virginia common law fraud. The Consumer Credit and Protection Act expressly directed that "the courts be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters." *Id.* at *2 (*quoting* W.Va. Code § 46A-6-101(1)). After the Medicaid and common law actions were dismissed with prejudice, the West Virginia attorney general sought to remand the case to state court, arguing that, with the resolution of the Medicaid claim, there was no longer a federal question. The court disagreed, holding that, because of the statutory incorporation of federal court and agency interpretations, any court applying the statute "must necessarily look to federal statutes and federal court decisions in its analysis." *Id.* at *3. In applying the *Grable* test, the court took note of the "[m]any states with claims" against the manufacturer "engaged in multi-district litigation," and reasoned that a "degree of national uniformity is desirable as these states' claims proceed." *Id.*

22. In a similar action, the attorney general of New Mexico filed suit under the New Mexico Unfair Practices Act, alleging that Zyprexa's manufacturer made intentionally misleading statements regarding off-label use of the drug Zyprexa and knowingly concealed the fact that the drug was unsafe for public use. *In re Zyprexa Prods. Liab. Litig.*, 2009 WL 691942 (E.D.N.Y. Mar. 11, 2009). Like West Virginia (and Mississippi), that statute stated that it "is the intent of the legislature that in construing . . . the Unfair Practices Act, the courts to the extent possible will be guided by the interpretations given by the federal trade commission [*sic*] and the federal courts." *Id.* at *3 (*quoting* N.M. Stat. Ann. § 57-12-4). Again, the state attorney general

sought remand for lack of a federal question, and again the court rejected the argument, citing to "the specific requirement that a court look to federal statutes and federal court decisions when applying" the state consumer protection law. *Id.* at *4.[6]

23. The allegations in the instant case under the MCPA mirror those in the above cases: "Publishing . . . material containing inaccurate and incomplete factual information . . . misrepresenting the alleged benefits of docetaxel . . . [and] failing to disclose the serious and dangerous side effects." Compl. at ¶ 234. Like the West Virginia and New Mexico statutes, the MCPA expressly incorporates the decisions of the FTC and the federal judiciary in applying the state law. Like both of the above cases, the matter before this Court involves a state attorney general enforcement action against pharmaceutical companies where the product in question is the subject of hundreds, if not thousands, of claims being managed in federal multi-district litigation that are making essentially the same legal and factual allegations. And like both cases above, a central—and federal—question here is whether the alleged consumer protection violations would be considered wrongful conduct in the eyes of the federal system.

24. In light of this precedent, the four-part test under *Tennessee Gas Pipeline* (applying *Grable*) clearly warrants federal question jurisdiction in this case: Section 75-24-3(c) mandates that the Court resolve a federal issue in order to adjudicate Plaintiff's state law claim; the federal question—*i.e.* what constitutes "unfair or deceptive trade practices" according to the FTC and federal courts—is both disputed and substantial; and given that the Eastern District of

[6] Sanofi notes that other courts would appear to have reached the opposite conclusion regarding federal question. *See, e.g., Hood v. Ortho-McNeil-Janssen Pharms., Inc.*, 2009 WL 561575 (N.D. Miss. Mar. 4, 2009), and cases cited therein. A key distinguishing factor in all of these cases, however, is that all of them involved alternate recovery grounds—specifically, the Medicaid fraud statute and state statutory or common law fraud—and those courts based their decisions to remand on the application of those alternate grounds. None of them reached or addressed the issue raised by Section 75-24-3(c). In the present case, there is no other cause of action pled by Plaintiff—just the MCPA. Thus, Sanofi urges the Court to follow the decisions of other courts that have actually addressed the federal question issue in light of Section 75-24-3(c)-style statutes.

Louisiana is already handling *over ten thousand* docetaxel claims in the MDL, the movement of one additional case to federal court will not disturb the appropriate federal-state balance of the courts.

25. Nothing in this Notice of Removal shall be interpreted as a waiver, estoppel, preclusion or relinquishment of Sanofi's ability or right to assert any claim, counterclaim, cross-claim, third party claim, defense or affirmative matter, including, but not limited to: (1) lack of jurisdiction over the person; (2) improper venue; (3) insufficiency of process; (4) insufficiency and/or failure of service of process; (5) improper joinder of claims and/or parties; (6) failure to state a claim; (7) failure to join an indispensable party(ies); (8) waiver, (9) contractual, statutory, common law or other right to defense, indemnity, contribution or apportionment; or (10) any other pertinent claim or defense available under Miss. or Fed. R. Civ. P. 12, any state or federal statute or otherwise.

IV. CONCLUSION

26. WHEREFORE, Sanofi U.S. Services, Inc.; Sanofi-Aventis U.S. LLC; and Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S. respectfully remove this action from the Chancery Court of Hinds County in the State of Mississippi, bearing the Case Number G2018-1453, to this Court.

Dated: December 5, 2018

Respectfully submitted,

SANOFI U.S. SERVICES, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI-AVENTIS U.S. LLC d/b/a WINTHROP U.S.

By: */s/ R. David Kaufman*
R. David Kaufman, One of Their Attorneys

OF COUNSEL:

R. David Kaufman, MSB No. 3526
M. Patrick McDowell, MSB No. 9746
BRUNINI, GRANTHAM, GROWER & HEWES, PLLC
P.O. Drawer 119
Jackson, MS 39205
Telephone: (601) 948-3101
Facsimile: (601) 960-6902
dkaufman@brunini.com
pmcdowell@brunini.com

CERTIFICATE OF SERVICE

This is to certify that on this 5th day of December, 2018, a true and correct copy of the foregoing was filed by the Court's CM/ECF system, and a copy was sent via email to:

George W. Neville
Don Kilgore
Jacqueline H. Ray
Special Assistant Attorneys General
550 High Street, Suite 1200
Jackson, MS Suite 1200
gnevi@ago.state.ms.us
dkilg@ago.state.ms.us
jacra@ago.state.ms.us
Attorneys for Plaintiff

Matthew Mestayer
James R. Reeves
Reeves & Mestayer, PLLC
160 Main Street
Biloxi, MS 39530
mgm@rmlawcall.com
jrr@rmlawcall.com
Attorneys for Plaintiff

Pieter Teeuwissen
Simon & Teeuwissen
621 W. Northside Dr.
Jackson, MS 39206
adwoodard@bellsouth.net
Attorneys for Plaintiff

Walter T. Johnson
John B. Howell III
Watkins & Eager PLLC
The Emporium Building
400 East Capitol Street # 300
Jackson, Mississippi 39201
wjohnson@watkinseager.com
jhowell@watkinseager.com
Attorneys for Defendants Hospira, Inc., Hospira Worldwide LLC f/ka Hospira Worldwide, Inc., and Pfizer Inc.

Ronald G. Peresich
Randi P. Mueller
Page, Mannino, Peresich & McDermott, P.L.L.C.
759 Howard Avenue
P.O. Drawer 289
Biloxi, MS 39533-0289
R.J.Peresich@pmp.org
Randi.Mueller@pmp.org
Attorneys for Defendants Actavis LLC f/k/a Actavis Inc., Actavis Pharma, Inc. and Sagent Pharmaceuticals, Inc.

Jackson R. Sharman
Lana A. Olson
Lightfoot, Franklin & White, LLC
The Clark Building
400 N. 20th St.
Birmingham, AL 35203
jsharman@lightfootlaw.com
lolson@lightfootlaw.com
Attorneys for Defendant McKesson Corporation d/b/a McKesson Packaging

P. Ryan Beckett
La'Toyia Slay
Butler Snow, LLP
1020 Highland Colony Pkwy.
P.O. Box 6010
Ridgeland, MS 39158-6010
Ryan.beckett@butlersnow.com
Latoyia.slay@butlersnow.com
Attorneys for Accord Healthcare, Inc.

J. Carter Thompson
Baker Donelson Bearman Caldwell & Berkowitz, PC
P.O. Box 14167
Jackson, MS 39236-4167
cthompson@bakerdonelson.com
Attorneys for Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. and Sandoz Inc.

/s/ R. David Kaufman
Attorney for Defendants Sanofi U.S. Services, Inc.; Sanofi-Aventis U.S. LLC; and Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S.